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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Data System for Organ Procurement and Transplantation Network, OMB No. 0915-0157 – Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with of the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].**

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review - Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Samantha Miller, the acting HRSA Information Collection Clearance Officer at paperwork@hrsa.gov or call (301) 443-9094.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Data System for Organ Procurement and Transplantation Network, OMB No. 0915-0157 - Revision

Abstract: Section 372 of the Public Health Service Act requires that the Secretary, by contract, provide for the establishment and operation of a private, non-profit entity: the Organ Procurement and Transplantation Network (OPTN). The data collected pursuant to the OPTN's regulatory authority in 42 CFR 121.11 of the OPTN Final Rule will be collected through OMB-approved data collection forms. Therefore, data approved for collection by the OPTN Board of Directors are submitted by HRSA for OMB approval under the Paperwork Reduction Act of 1995.

A 60-day notice was published in the Federal Register, 86 FR 48743 (Aug. 31, 2021). One comment was received. The commenter supported the necessity and utility of the proposed information collection and the use of automated collection techniques. The commenter recommended that HRSA account for anticipated increased staff hours and recommended emphasizing collecting data pertaining to race, ethnicity, social determinants of health, and any other characteristics that will help achieve equity in organ donation and transplantation. HRSA appreciates all feedback, and we will continue to review and evaluate all data collection efforts going forward in consultation with the OPTN.

The 60-day notice proposed data collection changes to existing data collection forms related to Vascularized Composite Allograft (VCA) transplantation, to implement policies approved by the OPTN Board of Directors. The OPTN expects to make additional changes to these VCA data collection forms in the near future so implementation of data collection changes has been postponed. These data collection changes are not included in this 30-day notice and will be included for review in a future submission.

Need and Proposed Use of the Information: Data are used to develop transplant, donation, and allocation policies, to determine whether institutional members are complying with policy, to determine member-specific performance, to ensure patient safety, and to fulfill the requirements of the OPTN Final Rule. The practical utility of the data collection is further enhanced by requirements that the OPTN data must be made available, consistent with applicable laws, for use by OPTN members, the Scientific Registry of Transplant Recipients, the Department of Health and Human Services, and members of the public for evaluation, research, patient information, and other important purposes.

This is a request to revise the current OPTN data collection associated with an individual's clinical characteristics at the time of registration, transplant, and follow-up after the transplant to include data collection forms in the OPTN Organ Labeling, Packaging, and Tracking System, the OPTN Kidney Paired Donation Pilot Program (KPDPP), and the OPTN Patient Safety Reporting Portal (PSRP). This revision also includes OPTN Board of Directors-approved changes to the existing OMB data collection forms. These specific data elements of the OPTN data system are collected from transplant hospitals, organ procurement organizations, and histocompatibility laboratories. The information is used to (1) facilitate organ placement and match donor organs with recipients; (2) monitor compliance of member organizations with Federal laws and regulations and with OPTN requirements; (3) review and report periodically to the public on the status of organ donation and transplantation in the United States; (4) provide data to researchers and government agencies to study the scientific and clinical status of organ

transplantation; (5) perform transplantation-related public health surveillance including the possible transmission of donor disease.

HRSA is submitting the following changes to improve the OPTN organ matching and allocation process and improve OPTN member compliance with OPTN requirements. All of these proposed changes have been approved by the OPTN Board of Directors.

1) Adding data collection forms for the OPTN Organ Labeling, Packaging, and Tracking System to the existing OMB-approved Data System for Organ Procurement and Transplantation Network. The system has two forms that are used through mobile and web-based applications to ensure the correct organ is transplanted into the correct patient, minimize labeling and transport errors, accelerate organ information transfer, and capture data regarding organ procurement. OPTN Organ Labeling, Packaging and Tracking System is comprised of two data collection forms: organ labeling and packaging, and organ tracking and validating.
2) Adding data collection forms for the OPTN KPDPP to the existing OMB-approved Data System for Organ Procurement and Transplantation Network. Kidney paired donation is a transplant option for those patients waiting for a kidney transplant who have a willing living donor who is medically able but cannot donate a kidney to their intended candidate because they are incompatible. OPTN KPDPP matches living donors, and their intended candidates with other living donors or intended candidate pairs when the living donors cannot donate to the person(s) they initially hoped would receive their kidney. OPTN KPDPP is comprised of three data collection forms: candidate registration, donor registration, and match offer management.
3) Adding data collection forms in the OPTN PSRP to the existing OMB-approved Data System for Organ Procurement and Transplantation Network. OPTN PSRP allows the OPTN to collect reports on any event or process variance that could cause concerns from transplantation, donation, safety, or quality perspective. OPTN PSRP is comprised of

four data collection forms: disease transmission event, living donor event, safety situation, and potential disease transmission.

4) Adding a request to unlock form
5) Additional revisions to existing data collection forms were made based on the OPTN Board of Directors-approved changes to improve organ matching, allocation, and OPTN policy compliance.

Likely Respondents: Transplant programs, Organ Procurement Organizations, and Histocompatibility Laboratories.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

The total burden hours in the OMB inventory increased by 4,337 hours from the previously OMB-approved data collection package from August 25, 2020. This increase is due to including new data collection forms and additional data to existing data collection forms. However, the total burden hours of this request is less than the total burden hours presented in the 60-day notice, because of the removal of the proposed data collection changes associated with implementing the “Modify Data Collection on VCA Living Donors” and “Programming VCA Allocation in UNet” policies.

Total Estimated Annualized Burden - Hours

Form Name	Number of Respondents	Number of Responses per Respondent*	Total Responses	Average Burden per Response (in hours)	Total Burden Hours
Deceased Donor Registration	57	188.26	10,731	1.10	11,804
Living Donor Registration	300	22.85	6,855	1.80	12,339[a]
Living Donor Follow-up	300	62.23	18,669	1.30	24,270[b]
Donor Histocompatibility	147	123.99	18,226	0.20	3,645
Recipient Histocompatibility	147	225.10	33,090	0.40	13,236
Heart Candidate Registration	140	33.69	4,717	0.90	4,245
Heart Recipient Registration	140	24.33	3,406	1.20	4,087
Heart Follow Up (6 Month)	140	22.01	3,081	0.40	1,232
Heart Follow Up (1-5 Year)	140	90.61	12,685	0.90	11,417
Heart Follow Up (Post 5 Year)	140	153.97	21,556	0.50	10,778
Heart Post-Transplant Malignancy Form	140	12.77	1,788	0.90	1,609
Lung Candidate Registration	71	45.21	3,210	0.90	2,889
Lung Recipient Registration	71	35.66	2,532	1.20	3,038
Lung Follow Up (6 Month)	71	32.35	2,297	0.50	1,148
Lung Follow Up (1-5 Year)	71	118.85	8,438	1.10	9,282

Form Name	Number of Respondents	Number of Responses per Respondent*	Total Responses	Average Burden per Response (in hours)	Total Burden Hours
Lung Post-Transplant Malignancy Form	71	19.72	1,400	0.40	560
Heart/Lung Candidate Registration	69	0.97	67	1.10	74
Heart/Lung Recipient Registration	69	0.46	32	1.30	42
Heart/Lung Follow Up (6 Month)	69	0.45	31	0.80	25
Heart/Lung Follow Up (1-5 Year)	69	1.14	79	1.10	87
Heart/Lung Follow Up (Post 5 Year)	69	3.30	228	0.60	137
Heart/Lung Post-Transplant Malignancy Form	69	0.30	21	0.40	8
Liver Candidate Registration	146	90.29	13,182	0.80	10,546
Liver Recipient Registration	146	56.55	8,256	1.20	9,907
Liver Follow-up (6 Month - 5 Year)	146	266.57	38,919	1.00	38,919
Liver Follow-up (Post 5 Year)	146	316.61	46,225	0.50	23,113
Liver Recipient Explant Pathology Form	146	10.58	1,545	0.60	927
Liver Post-Transplant Malignancy	146	16.35	2,387	0.80	1,910
Intestine Candidate Registration	20	6.95	139	1.30	181
Intestine Recipient Registration	20	5.20	104	1.80	187
Intestine Follow Up (6 Month - 5 Year)	20	26.20	524	1.50	786
Intestine Follow Up (Post 5 Year)	20	37.20	744	0.40	298
Intestine Post-Transplant Malignancy Form	20	2.10	42	1.00	42
Kidney Candidate Registration	237	168.77	39,998	0.80	31,998
Kidney Recipient Registration	237	89.43	21,195	1.20	25,434

Form Name	Number of Respondents	Number of Responses per Respondent*	Total Responses	Average Burden per Response (in hours)	Total Burden Hours
Kidney Follow-up (Post 5 Year)	237	449.40	106,508	0.50	53,254
Kidney Post-Transplant Malignancy Form	237	22.64	5,366	0.80	4,292
Pancreas Candidate Registration	133	2.77	368	0.60	221
Pancreas Recipient Registration	133	1.46	194	1.20	233
Pancreas Follow-up (6 Month - 5 Year)	133	7.87	1,047	0.50	524
Pancreas Follow-up (Post 5 Year)	133	15.93	2,119	0.50	1,060
Pancreas Post-Transplant Malignancy Form	133	0.73	97	0.60	58
Kidney/Pancreas Candidate Registration	133	9.75	1,297	0.60	778
Kidney/Pancreas Recipient Registration	133	7.73	1,028	1.20	1,234
Kidney/Pancreas Follow-up (6 Month - 5 Year)	133	32.80	4,362	0.50	2,181
Kidney/Pancreas Follow-up (Post 5 Year)	133	57.80	7,687	0.60	4,612
Kidney/Pancreas Post-Transplant Malignancy Form	133	2.20	293	0.40	117
VCA Candidate Registration	27	0.89	24	0.40	10
VCA Recipient Registration	27	1.59	43	1.30	56[c]
VCA Recipient Follow Up	27	0.67	18	1.00	18[d]
Organ Labeling and Packaging System	57	208.25	11,870	0.18	2,137
Organ Tracking and Validating System	34	169.06	5,748	0.08	460
Kidney Paired Donation Candidate Registration	160	1.38	221	0.29	64
Kidney Paired Donation Donor Registration	160	1.46	234	1.07	250
Kidney Paired Donation Match Offer Management	160	1.51	242	0.67	162
Form Name	Number of Respondents	Number of Responses per Respondent*	Total Responses	Average Burden per Response (in hours)	Total Burden Hours

Living Donor Event	251	0.12	30	0.56	17
Safety Situation	450	0.48	216	0.56	121
Potential Disease Transmission Report	57	6.88	392	1.27	498
Request to Unlock Form	450	39.22	17,649	0.02	353
Total	**8,290**		**604,519**		**430,267**

*The Number of Reponses per Respondent was calculated by dividing the Total Responses by the Number of Respondents and rounding to the nearest tenth.

a), b), c), d) Total burden hours in these forms decreased from estimates provided in the 60-day Notice due to the removal of the proposed data collection changes associated with implementing the "Modify Data Collection on VCA Living Donors" and "Programming VCA Allocation in UNet" policies.

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Maria G. Button,

Director, Executive Secretariat.

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